77. **(Amended Twice)** A pharmaceutical composition comprising:

i) an estrogen in a sufficient amount to treat diseases, disorders and symptoms associated with deficient endogenous levels of estrogen in women

ii) drospirenone in micronised form and in a sufficient amount to protect the endometrium from the adverse effects of estrogen; and

iii) a pharmaceutically acceptable excipient or carrier.

86. **(Amended)** A composition according to claim 77, wherein the dose of drospirenone corresponds to 15 to 70 mg per cycle.

87. **(Amended)** A composition according to claim 77, wherein the amount of drospirenone corresponds to a daily dose ranging from 0.25 to 10 mg.

88. **(Amended)** A composition according to claim 83, wherein the amount of estradiol corresponds to a daily dose ranging from 0.1 to 5 mg.

89. **(Twice Amended)** A pharmaceutical composition comprising:

i) estradiol in an amount corresponding to a daily dose of 1 to 3 mg to treat diseases, disorders and symptoms associated with deficient endogenous levels of estrogen in women,

ii) drospirenone in micronised form and in an amount corresponding to a daily dose of 1 to 3.5 mg to protect the endometrium from the adverse effects of estrogen, and

iii) a pharmaceutically acceptable excipient or carrier.

90. (Amended) A method of treating and preventing diseases, disorders and symptoms associated with deficient endogenous levels of estrogen in women comprising administering for at least one cycle of from 21 to 31 days;

an estrogen in a sufficient amount to alleviate said diseases, disorders and symptoms,

and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen,

said administering being by oral means.

97. (Amended) A method according to claim 90, wherein drospirenone is in micronized form.

100. (Amended) A method according to claim 90, wherein the dose of drospirenone corresponds to 15 to 70 mg per cycle.

101. (Amended) A method according to claim 90, wherein the amount of drospirenone corresponds to a daily dose ranging from 0.25 to 10 mg.

102. (Amended) A method according to claim 96, wherein the amount of estradiol corresponds to a daily dose ranging from 0.1 to 5 mg.

104. (Amended) A method according claim 90, comprising:

a first treatment period of 10 to 12 days comprising administering a daily dosage unit

comprising estradiol in an amount corresponding to a daily dose ranging from 0.1 to 5 mg;

following the first treatment period, a second treatment period of 10 to 12 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of from 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of from 0.25 to 6 mg; and

following the second treatment period, a third treatment period of 4 to 8 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of from 0.25 to 5 mg.

105. (Amended) A method according claim 90, comprising:

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a first treatment period of 10 to 12 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose ranging from 0.1 to 5 mg;

following the first treatment period, a second treatment period of 10 to 12 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of from 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of from 0.25 to 6 mg; and

following the second treatment period, a third treatment period of 4 to 8 days comprising administering a daily dosage unit of a placebo or blank.

106. (Amended) A method according to claim 90, comprising:

a first treatment period of at least 21 days comprising administering a daily dosage unit comprising estradiol an amount corresponding to a daily dose of from 0.1 to 5 mg and drospirenone in amount corresponding to a daily dose of from 0.25 to 6 mg; and

following the first treatment period, a second treatment period of no more than 7 days comprising administering a daily dosage unit of a placebo or blank.

107. (Amended) A method according to claim 90, comprising:

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a first treatment period of at least 21 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of from 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of from 0.25 to 6 mg; and

following the first treatment period, a second treatment period of no more than 7 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of from 0.1 to 5 mg.

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112. (Amended) A method according to claim 111, wherein the estrogen dosage is lower for the first 1 to 7 days immediately after finalizing said sequential administration of drospirenone.

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116. (Amended) A method according to claim 90, wherein the estrogen and the drospirenone are each administered sequentially with a treatment-free interval of 1-7 days within each cycle.

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117. (Amended) A method according to claim 90, comprising:

a first treatment period of administering for 20 to 24 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of from 0.1 to 5 mg, and drospirenone in an amount corresponding to a daily dose of from 0.25 to 6 mg for the last 10

to 12 days of said 20 to 24 days, and

following the first treatment period, administering for 4 to 8 days a daily dosage unit comprising no active ingredient.

118. **(Amended)** A method according to claim 90, comprising:

a first treatment period of administering for 20 to 24 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of from 0.1 to 5 mg, and drospirenone in an amount corresponding to a daily dose of from 0.25 to 6 mg for the last 10 to 12 days of said 20 to 24 days, and

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following the first treatment period, administering for 4 to 8 days a daily dosage of unit comprising estradiol in an amount less than daily dosage unit taken for said 20 to 24 day administration of estradiol.

119. (Amended) A method according to claim 90, comprising:

a first treatment period of administering for 20 to 24 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of from 0.1 to 5 mg, and drospirenone in an amount corresponding to a daily dose of from 0.25 to 6 mg for the last 10 to 12 days of said 20 to 24 days, and

following the first treatment period, not administering any dosage units for 4 to 8 days.

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122. (Amended) A method according to claim 104, wherein the daily dosage units are administered for 1 to 12 cycles of 28 days per cycle.

123. (Amended) A pharmaceutical composition consisting of a number of separately packaged and individually removable daily dosage units placed into a packaging unit and intended for oral administration for a period of at least 21 days wherein said daily dosage units comprise a combination of estradiol in an amount ranging from about 0.1 to 5 mg and drospirenone in an amount ranging from about 0.25 to 6 mg, the drospirenone being in micronized form or sprayed from a solution onto particles of an inert carrier.

124. (Amended) A pharmaceutical composition according to claim 123 consisting of a number of separately packaged and individually removable daily dosage units placed into a packaging unit and intended for oral administration for a period of 28 days.

125. (Amended) A pharmaceutical composition according to claim 124 consisting of a number of separately packaged and individually removable daily dosage units placed into a packaging unit and intended for oral administration for a period of 28 days, wherein at least 21 said daily dosage units comprise a combination of estradiol in an amount ranging from about 0.1 to 5 mg and drospirenone in an amount ranging from about 0.25 to 6 mg; and no more than 7 said dosage units comprise a placebo or a blank.

126. (Amended) A pharmaceutical composition according to claim 124, wherein at least 21 said daily dosage units comprise a combination of estradiol in an amount ranging from about 0.1 to 5 mg and drospirenone in an amount ranging from about 0.25 to 6 mg; and no more than 7 said dosage units comprise estradiol in an amount ranging from about 0.1 to 5

mg.

127. (Amended) A pharmaceutical composition according to claim 124, wherein at least 10 said daily dosage units comprise estradiol in an amount ranging from about 0.1 to 5 mg; and

at least 10 said daily dosage units comprise a combination of estradiol in an amount ranging from about 0.1 to 5 mg and drospirenone in an amount ranging from about 0.25 to 6 mg; and no more than 8 of said daily dosage units comprise a placebo or blank.

128. (Amended) A pharmaceutical composition according to claim 124, wherein at least 10 said daily dosage units comprise estradiol in an amount ranging from about 0.1 to 5 mg; and

at least 10 said daily dosage units comprise a combination of estradiol in an amount ranging from about 0.1 to 5 mg and drospirenone in an amount ranging from about 0.25 to 6 mg; and no more than 8 of said daily dosage units comprise estradiol in an amount ranging from about 0.1 to 5 mg.

129. (Amended) A pharmaceutical composition according to claim 123, consisting of a number of separately packaged and individually removable daily dosage units placed into a packaging unit and intended for oral administration for a period of 21 to 30 consecutive days, wherein 10 to 15 said daily dosage units comprise a combination of estradiol in an amount ranging from about 0.1 to 5 mg and drospirenone in an amount ranging from about 0.25 to 6 mg; and

10 to 15 said daily dosage units comprise estradiol in an amount ranging from about 0.1 to 5 mg.

130. (Amended) A pharmaceutical composition according to claim 123, wherein the number of daily dosage units is at least 21 or a multiple of 21.

131. (Amended) A pharmaceutical composition according to claim 123, wherein the number of daily dosage units is 28 or a multiple of 28.

132. (Amended) A pharmaceutical composition according to claim 123, wherein said daily dosage units comprise estradiol in micronized form or sprayed from a solution onto particles of inert carrier.

Add the following new claims:

133. The composition according to claim 77, wherein the composition is in a form selected from the group consisting of tablets, capsules and pills.

134. The method according to claim 90, wherein the estrogen and/or the drospirenone is administered in the form of a tablet, capsule or pill.

135. A composition according to claim 77, wherein the dose of drospirenone corresponds to 20 to 60 mg per cycle.

136. A composition according to claim 83, wherein the amount of estradiol corresponds to a daily dose ranging from about 0.2 to 4.5 mg.